



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of : Brodka-Pfeiffer, K. et al ) Art Unit: 1754  
U.S. Appln. No. : 10/617,546 ) Examiner: To be assigned  
Confirmation No. : 4289  
U.S. Filing Date : July 10, 2003  
Title of Invention : Process For Providing A Stable Crystalline Form Of Salbutamol  
Attny. Docket No. : 1/1367

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

December 8, 2003

**TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT**

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

The fee set forth in 37 C.F.R. §1.17(p).

The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No.

- 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).
- 1.97(e).
- Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or
- No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.
- The fee set forth in 37 C.F.R. §1.17(p).
- The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.
- 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.
- The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

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Respectfully submitted,



Alan R. Stempel  
Attorney for Applicant(s)  
Reg. No. 28,991

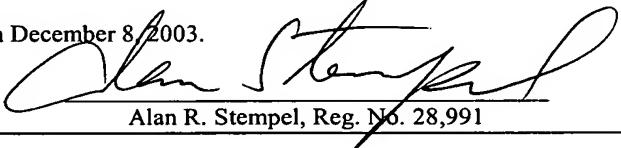
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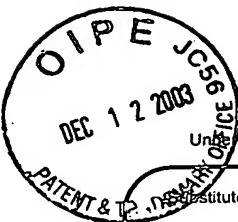
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Institute for form 1449B/PTOINFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

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of

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Complete if Known	
Application Number	10/617,546
Filing Date	July 10, 2003
First Named Inventor	Brodka-Pfeiffer, K. et al
Art Unit	1754
Examiner Name	To be assigned

Attorney Docket Number

1/1367

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		GARY H. WARD ET AL; Process-Induced Crystallinity Changes in Albuterol Sulfate and Its Effect on Powder Physical Stability; Pharmaceutical Research (1995) Vol. 12 No. 5 page 773-779; Plenum Publishing Corporation	
		CLAES AHLNECK ET AL; The Molecular basis of moisture effects on the physical and chemical stability of drugs in the solid state; International Journal of Pharmaceutics (1990) Vol 62 page 87-95; Elsevier Science Publishers B.V.	
		M.D. TICEHURST ET AL; Determination of the surface properties of two batches of salbutamol sulphate by inverse gas chromatography; International Journal of Pharmaceutics (1994) Vol. 111 page 241-249; Elsevier Science B.V.	
		LARS-ERIK BRIGGNER ET AL; The use of isothermal microcalorimetry in the study of changes in crystallinity induced during the processing of powders; International Journal of Pharmaceutics (1994) Vol. 105 page 125-135; Elsevier Science B.V.	
		AZITA SALEKI-GERHARDT ET AL; Assessment of disorder in crystalline solids; International Journal of Pharmaceutics (1994) Vol. 101 Page 237-247; Elsevier Science Publishers B.V.	
		TERENCE L. THRELFALL; Analysis of Organic Polymorphs A Review; Analyst October 1995 Vol. 120 page 2435-2460; Chemistry Department, University of York, Heslington, York UK	
		BRUNO C. HANCOCK ET AL; Characteristics and Significance of the Amorphous State in Pharmaceutical Systems; Journal of Pharmaceutical Sciences January 1997 Vol. 86 No. 1 page 1-12; American Pharmaceutical Association and the American Chemical Society	
		AMIN A ELAMIN ET AL; The use of amorphous model substances to study mechanically activated materials in the solid state; International Journal of Pharmaceutics (1995) Vol. 119 Page 25-36; Elsevier Science B.V.	
		TESFAI SEBHATU ET AL; Assessment of the degree of disorder in crystalline solids by isothermal microcalorimetry; International Journal of Pharmaceutics (1994) Vol. 104 page 135-144; Elsevier Science B.V.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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